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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/405,940 09/27/99 HILLMAN

J PF-0346-1-DI

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HM12/0404

EXAMINER

EWOLDT, G

ART UNIT

PAPER NUMBER

1644

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DATE MAILED:

04/04/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/405,940

Applicant(s)

Hillman et al.

Examiner

G. R. Ewoldt

Group Art Unit

1644

☒ Responsive to communication(s) filed on Jan 29, 2001

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1, 2, 13, and 24-26 is/are pending in the application.

Of the above, claim(s) 24-26 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1, 2, and 13 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Claims 1, 2, and 13 are being acted upon.
2. In view of Applicant's Amendment and Remarks, filed 1/29/01, only the following rejections remain.
3. 35 U.S.C. 101 reads as follows:
Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.
4. Claims 1, 2, and 13 stand rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility, for the reasons set forth in Paper No. 7, mailed 10/24/00.

Applicant's arguments, filed 1/29/01, have been fully considered but have not been found convincing. Applicant argues that the conclusions of the Mikayama et al. reference, previously cited by the Examiner, have not been repeated by other investigators, and that the conclusions of the Voet et al. reference comprise an exception and not the rule. While Applicant may dispute the particulars of the individual references, Applicant has provided no data demonstrating the inaccuracy of either reference. Applicant's submitted reference by Weiser et al., indicating that a publication concerning MIF has been retracted, is irrelevant, however, because the Mikayama et al. reference cited by the Examiner has not been retracted. Together said references serve to demonstrate a lack of credibility, and particularly, a specific amount of unpredictability of the art as it applies to the claimed invention.

Applicant further submits several additional references in support of the claimed invention. Applicant asserts that the newly submitted Brenner et al. and Bowie et al. references teach the use of sequence homology to establish conservation of protein structure and function. The Brenner et al. reference, however, merely asserts that they have developed a superior method for predicting relationships between proteins based on relationships that are already known. Mere assertion of "a better method", absent data, i.e., working examples, is insufficient to support the instant claims. Further, Applicant has not even established

that the analysis methods taught by the reference are the methods used in the analysis of the instant invention. Likewise, the Bowie et al. reference teaches the importance of considering structure as well as sequence - methods not employed in the instant application.

Regarding considerations of sequence only, Bork (2000) teaches that 70% accuracy in predicting function based on sequence homology "has to be considered a success," but even that number is often an "overestimate" and said 70% success rate relates only to simple "qualitative" features. Atwood (2000) sets an even more pessimistic tone, referring to structural and functional predictions based on sequence homology as "The Babel of Bioinformatics." The reference teaches an error rate of >80% in such predictions. Skolnick et al. (2000) teaches that sequence-to-function methods are of limited value and that the methods "will increasingly fail as the protein-sequence databases become more diverse." Further, "inaccurate use of the sequence-to-function methods has led to significant function-annotation errors in the sequence databases," i.e., use of the method perpetuates larger and larger errors.

Applicant's asserted utility is therefore not considered a specific and substantial asserted utility or a well-established utility.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1, 2, and 13 stand also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by a credible utility, for the reasons set forth above, one skilled in the art would not know how to use the claimed invention so that it would operate as intended without undue experimentation, for the reasons set forth in Paper No. 7, mailed 10/24/00.

Applicant's arguments, filed 1/29/01, have been fully considered but have not been found convincing, see paragraph 4 above.

7. Claim 2 stands rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention, for the reasons set forth in Paper No. 7, mailed 10/24/00.

Applicant's arguments, filed 1/29/01, have been fully considered but have not been found convincing. Applicant argues that the new claim language limiting the claimed protein to 90% sequence identity and IL-2 inducing activity is sufficient to overcome the previous rejection. However, said claim still encompasses a virtually unlimited number of proteins while the specification still provides an insufficient written description of said proteins.

8. No claim is allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday and alternate Fridays from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

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Art Unit 1644

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Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

G.R. Ewoldt, Ph.D.
Patent Examiner
Technology Center 1600
March 28, 2001



Patrick J. Nolan, Ph.D.
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